

2/26/95

**I. Summary of Safety and Effectiveness - 510(k) Summary**

K990443

W.O.M. GmbH  
Michael McGrail, Agent  
Kaiserin-Augusta-Allee 113  
D-10553 Berlin  
Germany.

Proprietary Name: Arthro-Surgimat-2000 ECU  
Common Name: Arthroscopic Pump

The ARTHRO-SURGIMAT-2000 ECU is a high flow arthroscopic pump intended to distend joint cavities. The ARTHRO-SURGIMAT-2000 ECU is a modified version of and substantially equivalent to the device Arthro-Surgimat-1500 (K983910) manufactured by W.O.M. GmbH. W.O.M. also claims substantial equivalence to the Surgiflator-20 ECU (K981859) and the Linvatec Apex Universal Irrigation System (K933873).

With the exception of the following modifications, the ARTHRO-SURGIMAT-2000 ECU incorporates the same design features and accessories as the Arthro-Surgimat-1500 (K983910):

- A serial interface has been incorporated in the device to allow for surgeon selection of device settings utilizing the HERMES Operating Room Control Center (K980787). The external adjustment capability of the ARTHRO-SURGIMAT-2000 ECU is substantially equivalent to the device Surgiflator-20 ECU (K981859) manufactured by W.O.M. GmbH
- The maximum flow performance of the device has been increased from 1,5 l/min. to 2 l/min. The flow performance of the ARTHRO-SURGIMAT-2000 ECU is substantially equivalent to the device Apex Universal Irrigation System (K933873) manufactured by Linvatec Corp.

The utility and safety of arthroscopic techniques using modern electronic high flow pumps is discussed in the following literature, including the benefits and risks of such procedures and the importance of effective, well maintained instrumentation.

A Comprehensive discussion of the use of distention methods is presented in the book "**Arthroscopic: Diagnostika und Therapie**" (1) by Harald Hempfling, 1995, in which the development of arthroscopic procedures is reviewed, including objective comparisons of arthroscopy vs. traditional methods of treatment. This extensive analysis of the instrumentation in this field includes comments on the use of modern high flow pumps, the selection of the optimal distention medium and a summary of other instruments necessary for arthroscopic procedures. (pg. 13-41).

This work is of particular interest due to the extensive review of arthroscopic techniques specific to various joints. This includes, but is not limited to, the knee, shoulder, wrist, and elbow.

„**Operative Arthroscopy, Second Edition**“ (2), provides an in-depth review of the history, techniques and modern apparatus of arthroscopic procedures. Of special interest is the chapter on advanced arthroscopic instrumentation (pg. 7-13), in which irrigation systems are also discussed in detail. Other references to irrigation systems include pg. 75 and pg. 256.

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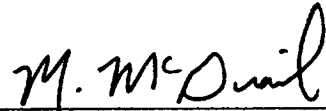
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Germany.

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**REFERENCES**

1. Hempfling, Harald. "Arthroscopie: Diagnostika und Therapie". Landsberg, Germany: Ecomed Verlagsgesellschaft AG + Co. KG, 1995, 375 pages.
2. McGinty, John B. "Operative Arthroscopy, Second Edition" Philadelphia: Lippincott-Raven Publishers, 1995, 1500 pages. See „Advanced Arthroscopic Instrumentation“ on pages 7-13.

Signed: \_\_\_\_\_



Michael McGrail  
Agent, W.O.M. GmbH



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Date: 02/08/99



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 26 1999

W.O.M. GmbH  
c/o Michael McGrail  
Regulatory Consultant  
194 Branch Street  
Mansfield, Massachusetts 02048

Re: K990443  
Trade Name: ARTHRO-SURGIMAT-2000 ECU  
Regulatory Class: II  
Product Code: HRX  
Dated: February 8, 1999  
Received: February 11, 1999

Dear Mr. McGrail:

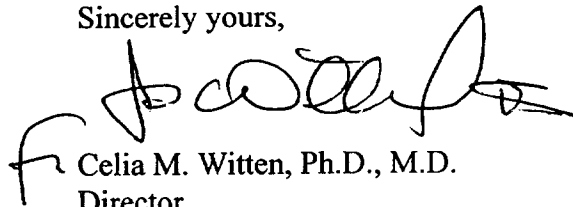
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**STATEMENT OF INDICATIONS FOR USE**

APPLICANT: W.O.M. GmbH

510(K) NUMBER (if known): K 990443

DEVICE NAME: ARTHRO-SURGIMAT 2000 ECU, for optional use  
with the HERMES Operating Room Control Center

**INDICATIONS-FOR USE:**

The Arthro-Surgimat-2000 ECU is a high flow arthroscopic pump intended for fluid distention of the knee, shoulder, elbow, ankle and wrist joint cavities under optional voice-activation control during arthroscopic procedures. (21 C.F.R. & 888.1100).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

Prescription Use X  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

  
(Division Sign-Off)

Division of General Restorative Devices  
510(k) Number K990443